DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville MD 20850

WARNING LETTER
VIA EXPRESS MAIL

JAN 12 2001

Soren Olesen
Managing Director
Pinol Finmekanik A/S
Engvej 33
DK-3330 Gorlose
Denmark

Dear Mr. Olesen:

We are writing to you because on September 11-13, 2000, an investigator from the Food and Drug Administration (FDA) collected information that revealed serious regulatory problems involving the products known as dental endosseous implants and the counter torque key, which are made and marketed by your firm. We are aware that you have corrected some of the deviations observed during the inspection of September 21-24, 1998, that resulted in a Warning Letter dated November 12, 1998. However some of the deviations observed during the 1998 inspection, such as inadequate validation of the ultrasonic cleaning and laser welding processes, were also observed during the most recent inspection.

Under a United States Federal law, the Federal Food, Drug, and Cosmetic Act (the Act), these products are considered to be medical devices because they are used to diagnose or treat a medical condition or to affect the structure or function of the body (Section 201(h) of the Act).

The above stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packaging, storage, or installation are not in conformance with the Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21 Code of Federal Regulations (CFR), Part 820, as follows:

1. The supplier of titanium used in Cresco endosseous implants has not been evaluated by either (a) supplier audits, or (b) independent laboratory confirmation of Certificates of Analysis as required by 21 CFR 820.50.

2. The validation of ultrasonic cleaning method [redacted] dated Sept. 4, 2000, was performed using stainless steel parts without threads. Method [redacted] has not been validated using titanium parts with external and internal threads, such as the Cresco endosseous implant as required by 21 CFR 820.75.

3. There is no established weld strength specification for the laser-welded Counter Torque Key, part #248-02 as required by 21 CFR 820.181.

4. The device master record for the Counter Torque Key does not include written process parameters for laser welding as required by 21 CFR 820.181.

5. The laser welding process for the Counter Torque Key has not been validated as required by 21 CFR 820.75.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulation. The specific violations noted in this letter and in the Inspectional Observation form, form FDA-483, issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the Food and Drug Administration. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Given the serious nature of these violations of the Act, the endosseous dental implants and counter torque key devices manufactured by Pinol may be detained upon entry into U.S. until these violations are corrected. In order to remove the devices from this detention, it will be necessary for you to provide a written response to the charges in this letter for our review. After we notify you that the response is adequate, it will be your responsibility to schedule an inspection of your facility. As soon as the inspection has taken place, and the implementation of your corrections has been verified your products may resume entry into this country.

According to the inspection report, you promised to have your corrective action plan completed by November 30, 2000. The Center for Devices and Radiological Health (CDRH)\Office of Compliance (OC) has not received your corrective action plan. Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you are taking to correct the violations, including an explanation of each step being taken to identify and make corrections to any underlying system problems necessary to assure that similar violations will not recur. Any and all documentation showing plans for correction should be included with your response to this letter. If documentation is not in English, please provide the English translation to facilitate our review.

Your response should be sent to the attention of Mr. Patrick B. Weixel, Dental, Ear, Nose, Throat (ENT), and Ophthalmic Devices Branch, at the letterhead address.

Sincerely yours,

Larry Spears
Acting Director
Office of Compliance
Center for Devices and Radiological Health